

Package leaflet: Information for the patient

Hydrea 500 mg Hard Capsules

Hydroxycarbamide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Hydrea (Capsules) is and what it is used for
2. What you need to know before you take Hydrea
3. How to take Hydrea
4. Possible side effects
5. How to store Hydrea
6. Contents of the pack and other information

1. What Hydrea is and what it is used for

The name of your medicine is Hydrea. Each capsule contains hydroxycarbamide as the active ingredient. Hydroxycarbamide belongs to a group of medicines called anti-neoplastic medicines. These medicines interfere with the growth of cancer cells.

Hydrea is used to treat some types of cancer such as cervical cancer; and a type of leukaemia called chronic myeloid leukaemia (CML). The precise reason why you are being given Hydrea is best discussed with your doctor.

2. What you need to know before you take Hydrea

Do not take Hydrea Capsules:

- if you are allergic to hydroxycarbamide or any of the other ingredients of this medicine (listed in section 6).
- if you have history of any **blood problems**
- if you have severe anaemia

Warnings and precautions

Talk to your doctor or pharmacist before taking Hydrea.

If haemolytic anaemia (disorder in which red blood cells are destroyed faster than they can be made) is detected when the blood tests are checked, your doctor will stop treatment with Hydrea.

Your doctor will do regular blood tests before and whilst you are taking Hydrea. You may need to control or treat the source conditions before starting treatment with Hydrea.

In long term use of Hydrea, secondary leukaemia has been reported. Skin cancer has been reported in patients receiving long term hydroxycarbamide. You should protect your skin from the sun and regularly inspect your skin yourself during the treatment and after discontinuation of the

therapy with hydroxycarbamide. Your doctor will also inspect your skin during routine follow-up visits.

If you have previously had radiotherapy, Hydrea can lead to pain or discomfort from inflammation of the mucous membranes at the irradiated site (mucositis). If the reaction is severe, your doctor may temporarily interrupt treatment with Hydrea. If it is extremely severe, irradiation dosage may, in addition, be temporarily postponed.

Talk to your doctor or pharmacist if you intend to be vaccinated.

Talk to your doctor or pharmacist before taking Hydrea if you have diabetes and are using a continuous glucose monitor (CGM) to test your blood glucose. Hydroxycarbamide (also known as hydroxyurea) may cause falsely high sensor glucose readings from certain sensors. This could result in using more insulin than needed, leading to low blood sugar (hypoglycaemia). Talk to the physician that prescribed your CGM about whether it is safe to use while you are taking Hydrea.

Drinking plenty of fluids during treatment is vital.

Take special care with Hydrea Capsules if:

- you have any **kidney or liver** problems
- you have **impaired bone marrow**
- you are **pregnant**, planning to become pregnant or are breast feeding
- you have ever suffered from **gout**
- you have leg ulcers
- you have previously received radiotherapy or chemotherapy, or are currently taking any other **medicines for cancer treatment**, especially interferon therapy
- you have folic acid deficiency

Children

There is limited experience with the use of Hydrea in this age group.

Other medicines and Hydrea

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- Antiretroviral medicines (those that inhibit or destroy a retrovirus such as HIV), e.g., didanosine, stavudine and indinavir. In patients treated with Hydrea combined with medicines against HIV-infection (didanosine, stavudine), inflammation of the pancreas and liver damage have occurred (in certain instances, these side effects have been fatal), along with affecting the nerves in the hands and feet (peripheral neuropathy).
- Myelosuppressive medicines (including chemotherapies) and radiation therapy can increase the risk of certain side effects.
- Some vaccines, if you recently had a vaccination or are planning to have one, tell your doctor. Concurrent use of Hydrea and live virus vaccines is not recommended, as it can increase the side effects of the vaccine, and mean an increased risk of serious infection, since the body's normal defense mechanisms can be impaired by treatment with Hydrea.

Hydrea can increase the concentration of uric acid in the blood. The dose of medicines used against high levels of uric acid, such as allopurinol, may therefore need to be changed.

Always tell your doctor about other medicines you may be taking or have recently taken including those obtained without a prescription as some medicines can affect each other's actions.

It may be necessary to adjust the dose of some medicines if they are taken at the same time as Hydrea.

Hydrea with food, drink and alcohol

You should check with your doctor before drinking alcohol to find out if it is advisable for you.

Pregnancy, breast-feeding and fertility

You should not take this medicine if you are pregnant, planning to become pregnant or are breastfeeding, unless your doctor recommends it.

When appropriate both male and female patients should discuss effective contraceptive measures before and during treatment with Hydrea. For male patients only, this medicine can affect the production of sperm so you might want to discuss the possibility of conservation (by storage of sperm) with your doctor.

When appropriate both male and female patients should discuss effective safe contraceptive measures before, during therapy, and for at least 3 months and 6 months respectively after treatment with Hydrea.

In addition, if you are pregnant, planning to be or breastfeeding you should not handle the capsules.

Driving and using machines

You may feel drowsy. You should not drive or operate any machinery unless it has been shown not to affect you and have discussed it with your doctor.

Hydrea contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains 11.7 mg sodium (main component of cooking/table salt) in each capsule. This is equivalent to 0.6% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Hydrea

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You may be instructed to take your medicine on either a daily basis or an irregular basis.

The recommended dose is 20-30 mg of Hydrea per kg of your bodyweight **once a day** or 80 mg per kg of your body weight **once every third day**.

Elderly patients may be more sensitive to the effects of Hydrea and may be given a lower dose.

You can take this medicine at any time of the day, before or after meals. The capsules should be swallowed whole with a glass of water. However, if you find it difficult to swallow them, the contents of the capsule can be emptied into a glass of water and taken immediately. If some of the powder floats on the surface of the water, **DO NOT WORRY** this is just filler from the capsule. Hydrea capsules must be treated with care. The following precautions can prevent exposure:

- Wash your hands with soap and water before and after handling the product or wear protective gloves.
- If the powder in the capsule leaks out of the capsule, it must be wiped up immediately with a damp disposable towel and disposed of in a closed container together with the empty capsule shell.
- Wash your hands thoroughly with water if the capsule breaks or dissolves.
- **DO NOT** inhale the contents of the capsules.

- People who are not taking Hydrea should not be exposed to it. Keep Hydrea away from children and pets.

While you are being treated with Hydrea it is important that you drink plenty of fluids. This will help your kidneys work well.

If you are going to have radiation therapy, this medicine will usually be started 7 days before starting radiation treatment.

You should keep taking your capsules until your doctor tells you to stop.

If you take more Hydrea than you should

If you take too many capsules you should go to your nearest hospital Casualty Department immediately and take the medicine carton with you. The symptoms of overdose include; soreness, swelling of hands and feet and redness of skin.

If you forget to take Hydrea

If you forget to take a dose of this medicine DO NOT take the missed dose at all. Take your next dose when it is due; DO NOT take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following symptoms, you should stop taking the capsules and tell your doctor immediately as these may be signs of an allergic reaction:

- swelling of the face, lips, tongue or throat
- Strong infection, tiredness and/or paleness, inexplicable bruises or bleeding; these symptoms can be a sign of reduced activity in blood-producing organs, a very common side effect (may affect more than 1 in 10 users).
- Sores on the skin; these symptoms can be a sign of inflammation in the skin blood vessels, a very common side effect (may affect more than 1 in 10 users).
- Breathing difficulties, like shortness of breath, especially with exertion, a persistent dry cough, fatigue, or chest discomfort can be a sign of the lungs being affected, a common side effect (may affect up to 1 in 10 users). If breathing problems occur due to allergic inflammation of the lung tissue, fever may occur with unknown frequency (frequency cannot be estimated from the available data). Fever caused by the medicine High fever with or without symptoms in the gastrointestinal canal, lungs, skeleton and muscles, liver and gall bladder, skin or heart and blood vessels have been reported from use of the medicine. These can occur several weeks after starting to take the medicine (frequency cannot be estimated from the available data)..

The following side effects have been seen in some people:

Very common: may affect more than 1 in 10 people

- blood disorders (reduction in white blood cells, red blood cells and platelets)
- lower back pain or pain in your side
- black tarry stools or blood in the stools
- absence or low amount of sperm in the semen (azoospermia or oligospermia).
- loss of appetite

- kidney problems
- skin changes and muscle weakness (dermatomyositis) - you may experience symptoms such as muscle tenderness, muscle weakness or tiredness (especially when climbing stairs, walking or rising from a chair etc), a rash on the face, hands or other parts of the body (which in some cases may be scaly, purple and raised).
- sores on the lips or mouth
- difficulty or pain passing urine, uric acid increased, blood urea increased, blood creatinine increased
- pancreatitis (can be fatal), sickness, diarrhoea, constipation, abdominal pain, irritation in the abdomen and/or digestive tract, stomatitis, mucositis
- weakness, loss of energy
- skin problems may occur including darkening of the skin, peeling of the skin, purple raised patches of skin and redness, nail disorder. There may be a worsening of existing redness or discomfort in the skin or mucous membranes if you have had radiation treatment in the past.
- temporary hair loss

Common: may affect up to 1 in 10 people

- numbness or tingling of hands or feet
- skin cancer
- headache
- problems with the flow of the bile (cholestasis), the bile which is made by the liver to aid in digestion of food may not flow properly. A build up of bile can cause itchiness, yellow skin, very dark urine and very pale stools
- inflammation of the liver (hepatitis) which causes flu-like symptoms, including tiredness, loss of appetite, fever, aching, and feeling sick/being sick, pressure or pain below the right ribs and might also include yellowing of the skin or eyes
- drowsiness, dizziness, fits, confusion or hallucinations (seeing, hearing or feeling things that are not there)

Rare: may affect up to 1 in 1000 people

- skin ulceration with severe infection
- tumour lysis syndrome (complications of substances released from treated cancer cells entering the blood)

Very rare: may affect up to 1 in 10000 people

- Inflammation of the skin causing red scaly patches and possibly occurring together with pain in the joints

Not known: frequency cannot be estimated from the available data

- Change in the colour of the nails
- Haemolytic anaemia

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydrea

Do not store your tablets above 25 °C.

Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the blister or carton after EXP.

The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children or pets.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Hydrea contains

- The active substance is hydroxycarbamide. Each hard capsule contains 500 mg hydroxycarbamide.
- The other ingredients are citric acid anhydrous, erythrosine (E127), gelatin, indigotine (E132), lactose monohydrate, magnesium stearate, sodium laurilsulfate (as processing aid), sodium phosphate, titanium dioxide (E171), yellow iron oxide (E172) and Opacode S-1-277002.

What Hydrea looks like and contents of the pack

Hydrea capsules are pink, opaque capsules with green, opaque caps, and 'CHP 500' printed on them in black.

Hydrea capsules are packed in blister packs of 100 capsules.

For any information about this medicine, please contact the Marketing Authorisation Holder.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

CHEPLAPHARM Arzneimittel GmbH

Ziegelhof 24

17489 Greifswald

Germany

Manufacturer

Latina Pharma S.p.A.,

Via Murillo, 7,

04013 Sermoneta (LT),

Italy.

or

Haupt Pharma Amareg GmbH

Donaustauer Straße 378,

93055 Regensburg

Germany

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